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REMARKS

Claims 1-12 are currently pending. Claims 1 and 12 have been amended for clarification purposes as noted below.

The Examiner rejected Claims 1-6, 11, and 12 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,507,792 to Mason et al ("Mason"). The Examiner also rejected Claims 1, 4-11, and 12 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 3,995,621 to Fletcher et al ("Fletcher") in view of U.S. Patent No. 4,111,209 to Wolvek et al ("Wolvek"). Moreover, Claims 1-4, 6-11, and 12 are rejected under 35 U.S.C. § 103(a) as unpatentable over Mason in view of Wolvek.

Claim 1 has been amended to recite a closed loop heating system for a nipple aspirate fluid aspiration device, comprising a plurality of inflatable bladders in a series flow path configured to provide compression of a breast; a reservoir; and a fluid flow path comprising an inflow line and an outflow line for placing the bladders in fluid communication with the reservoir; wherein said closed loop system does not comprise a pump; wherein the entire closed loop heating system can be operated and removed without exposing a fluid within said closed loop to the outside of the closed loop system; and wherein said fluid flow path comprises a movable wall such that fluid in the system can be moved by application of external pressure to the movable wall.

Claim 12 has been amended to recite an array of inflatable bladders for use in a breast pump, comprising at least a first and a second inflatable bladder in a series flow path configured to provide compression of a breast; a mechanical link between the first and second bladder; a flow path extending between the first and second bladder; a reservoir; and a flow path comprising an inflow line and an outflow line between the reservoir and the first and second bladder; said flow path comprising a movable wall such that a fluid in the system can be moved by application of external pressure to the movable wall; wherein the array is adapted to cooperate with but does not include a pump; and wherein said array can be operated with the pump and removed from operative association with the pump without exposing the fluid within said array to the outside of the array of inflatable bladders.

Applicants note that basis in the original disclosure for amendments to both Claims 1 and 12 can be found, for example, at paragraphs [0104], [0108], [0121], [0133] and [0136] and

Figures 9 and 12 of the specification, and is thus proper under 35 U.S.C. § 112, paragraph 1. Furthermore, Applicants submit that the recitations in the amendments are proper under M.P.E.P. § 2173.05(i).

Rejections under 35 U.S.C. § 102(b)

Claims 1-6, 11, 12

Claims 1-6, 11, and 12 have been rejected as anticipated by Mason. Although Applicants do not necessarily acquiesce to the rejections, Claims 1 and 12 have been amended herein for clarification purposes. Applicants respectfully submit that Mason fails to identically teach every element of the claims, as amended herein. See M.P.E.P. § 2131 (stating that in order to anticipate a claim, a prior art reference must identically teach every element of the claim). Amended Claim 1 recites a closed loop heating system for a nipple aspirate fluid aspiration device, comprising a plurality of inflatable bladders in a series flow path configured to provide compression of a breast; a reservoir; and a fluid flow path comprising an inflow line and an outflow line for placing the bladders in fluid communication with the reservoir; wherein said closed loop system does not comprise a pump; wherein the entire closed loop heating system can be removed without exposing a fluid within said closed loop to the outside of the closed loop system; and wherein said fluid flow path comprises a movable wall such that fluid in the system can be moved by application of external pressure to the movable wall.

Mason discloses a therapeutic treatment device 10 with a fluid-retaining heat transfer element 12, a fluid reservoir 14, and a unitary tubular sheath 16 enclosing a pair of fluid lines 18, 20 extending between the pad 12 and the fluid reservoir 14. The pad 12 has a laminar construction with a flowpath 54 that is tortuous due to a plurality of circular welds 56 (col. 7, ll. 55-67). The device further comprises a pump 22 which may be an elastomeric bulb 22 positioned in-line across the inlet line 18 relatively distal to both the pad 12 and the fluid reservoir 14, or an in-line electrically powered, motor-driven pump 102 in another embodiment, along with a control knob 108 to adjust the cross-sectional area of the flowpath across a flow restrictor valve (col. 10, ll. 53-59, col. 12, ll. 1-20, Fig. 5). In yet another embodiment (described in connection with Fig. 8) Mason discloses is a larger volume bladder 302 having a single port 304 in fluid communication with the fluid flow line 202.

Applicants contend that Mason fails to disclose, inter alia, a plurality of inflatable bladders in a series flow path configured to provide compression of a breast; and a fluid flow path comprising an inflow line and an outflow line for placing the bladders in fluid communication with the reservoir; wherein said closed loop system does not comprise a pump; wherein the entire closed loop heating system can be operated and removed without exposing a fluid within said closed loop to the outside of the closed loop system; and wherein said fluid flow path comprises a movable wall such that fluid in the system can be moved by application of external pressure to the movable wall, as defined in the specification of the present application. Applicants note that the pad 12 of Mason, as shown in Figure 1, has a tortuous flowpath 54 with a plurality of circular welds 56 (col. 7, ll. 55-67) rather than the series flow path recited in Claim 1, and there is no discussion that the pad 12 may be configured for compression of a breast. In the embodiment shown in Figure 8 of Mason, the single large-volume bladder 302 is shown having a single port 304 in fluid communication with the fluid flow line 202. Again, there is no suggestion that any of the pads 12 or bladders 302 disclosed may be configured for compression of a breast. Furthermore, various embodiments of Mason disclose either an in-line bulb pump 22 or submersible pump 102 within the fluid flow path of the system, contrary to the recitation of Claim 1 that the closed loop system does not comprise a pump.

Furthermore, Applicants also note the specification discloses special advantages of the closed circuit fluid flow path as claimed. This closed loop structure may be easily removed from the associated pump and related electronics and replaced by a fresh closed loop part. The user does not need to come in contact with the heat exchange and inflation liquid. Nor does any part of the pump or associated device. This keeps the inflation media separate from any moisture-sensitive electronics (paragraph [0136]). Also, such a closed loop path conveniently also allows compression cycles such as from peristaltic rollers to be directly applied to the outside wall of the closed loop heating system, so that the pump never comes into direct contact with heat exchange fluid either during normal operation or during replacement of the closed loop. Furthermore, such a path may also allow compression cycles to be nonperistaltic cycles that are pulsatile within each cycle, such as the use of a platen or roller pump to provide pulsatile inflation of the inflatable bladders.

Therefore, it is not possible to exchange a single closed loop component in the devices of Mason while preventing direct contact between the heat or pressure exchange fluid and all other parts of the system both during operation and during replacement of the closed loop. Because the distinct characteristics defining the closed fluid flow loop as claimed are absent in the cited prior art references, Claim 1 is not anticipated by any of the aforementioned references. We thus request that the Examiner withdraw this rejection. Applicants note that Claims 2-6 and 11 depend from Claim 1 and contain all of the limitations thereof in addition to further distinguishing features; thus Applicants submit that these claims are in condition for allowance as well.

Claim 12

Claim 12 has also been rejected as anticipated by Mason. Applicants respectfully traverse this rejection because Mason fails to identically teach every element of the amended claim. Claim 12 has been amended to recite an array of inflatable bladders for use in a breast pump, comprising at least a first and a second inflatable bladder in a series flow path configured to provide compression of a breast; a mechanical link between the first and second bladder; a flow path extending between the first and second bladder; a reservoir; and a flow path comprising an inflow line and an outflow line between the reservoir and the first and second bladder; said flow path comprising a movable wall such that a fluid in the system can be moved by application of external pressure to the movable wall; wherein the array is adapted to cooperate with but does not include a pump; and wherein said array can be operated with the pump and removed from operative association with the pump without exposing the fluid within said array to the outside of the array of inflatable bladders.

Applicants reiterate here the discussion of Claims 1-6 and 11 above, and contend that Mason does not teach or even suggest, inter alia, a removable, closed loop system comprising at least a first and a second inflatable bladder in a series flow path configured to provide compression of a breast; a mechanical link between the first and second bladder and a flow path comprising an inflow line and an outflow line between the reservoir and the first and second bladder; said flow path comprising a movable wall such that a fluid in the system can be moved by application of external pressure to the movable wall; wherein the array is adapted to cooperate with but does not comprise a pump; and wherein said array can be operated with the pump and

removed from operative association with the pump without exposing the fluid within said array to the outside of the array of inflatable bladders. Therefore, because the distinct characteristics defining the array and fluid flow path are absent in the cited prior art reference, Claim 12 is not anticipated by Mason. We thus request that the Examiner withdraw this rejection.

Rejections under 35 U.S.C. § 103(a)

The Examiner rejected Claims 1 and 4-12 as unpatentable over Fletcher in view of Wolvek, and Claims 1-4 and 6-12 as unpatentable over Mason in view of Wolvek. Although Applicants do not necessarily acquiesce to the rejections, Claims 1 and 12 have been amended herein for clarification purposes. Applicants request that the obviousness rejection be withdrawn because neither reference teaches or suggests all of the recited claim limitations as amended. Furthermore, Applicants submit that one of ordinary skill of the art would have no motivation to produce the claimed features of the present application from either reference cited. See M.P.E.P. § 2143.

Fletcher in view of Wolvek

Claims 1, 4-11

Claims 1 and 4-11 have been rejected as unpatentable over Fletcher in view of Wolvek. Fletcher discloses cooling panels with a multiplicity of individual sections 20 connected to cooling liquid inlet line 24 and to cooling liquid outlet line 25 through a connecting Y coupler 26. Each panel has an inlet tube 32 and outlet tube 33 connected to the outlet cooling line 25 and the inlet cooling line 24, respectively (see col. 3, ll. 40-46, Fig. 2). The cooling fluid from pumping means 40, which is preferably a water pump, flows under pressure to a solenoid valve 41, and there the flow is routed either to bypass line 43 or through refrigeration unit 42. Heating means 44 receives the cooling fluid from either bypass line 43 or refrigeration unit 42. Cooling fluid then flows to reservoir 47 then into inlet line of the brassiere 24 (see col. 4, ll. 27-40, Fig. 4).

Wolvek discloses a disposable coolant circuit 12 with a pump 16 operating completely externally to the coolant circuit 12. Also described is a heat exchange portion 20 within a container 26 integral with the remainder of the coolant fluid circuit 12 (col. 3, l. 66-col. 4, l. 5;

col. 4 l. 53-col. 5 l. 5; col. 5,. ll. 40-52). The coolant circuit 12, heat exchange portion 20 and container 26 may be easily disassociated from the pump 16 and are preferably disposable. However, in order for the "closed loop" coolant circuit 12 to become operational in Wolvek's disclosure, coolant fluid 94 must be introduced via a multiple-step process. Coolant fluid 94 is introduced via an infusion line 96 and passage 92b after adjustment of a petcock 90. During this time, a bag 22 is prevented from expanding by being held by an operator or maintained in a disposable sleeve. When the coolant circuit has been completely filled (except for bag 22) as evidenced by overflow from the open end 18g of the tubing 18, the petcock 90 is turned off and the tubing end 18g is reconnected to passage 12a of the petcock 90. Infusion line 96 is then removed from petcock passage 92b. Next, the deflated bag 22 is located in the bodily cavity and additional fluid is added via a syringe 98 coupling the passage 92b of the petcock 90. Finally, opening the petcock will thus distend the bag 22 (col. 6, ll. 20-60). At the end of the procedure, a suction line is connected to passage 92b of petcock 90 in order to completely empty the coolant circuit 12 of coolant fluid and thereby deflate the bag 22, before it is removed from the cavity. The coolant circuit 12 and container 26 may then be discarded (col. 7, ll. 10-16).

Applicants contend that Claims 1 and 4-11 would not have been obvious because even the combination of Fletcher and Wolvek fails to teach or suggest all of the recited claim limitations, inter alia, a closed loop heating system comprising a plurality of inflatable bladders in a series flow path configured to provide compression of a breast and wherein entire said closed loop heating system can be operated and removed without exposing a fluid within said closed loop to the outside of the closed loop system. There is no teaching or suggestion that the device of Fletcher, comprising planar panels for cooling a breast, may be structurally configured to provide compression of a breast. Wolvek does not make up for this deficiency. Moreover, Fletcher's disclosed device is not a closed loop system as defined in the application, having an in-line pump 40, as well as an inlet tube 24 and outlet tube 25 that must be connected (and disconnected) to the pumping-thermal control system, exposing a fluid to the outside of the system (col. 5, ll. 5-10). Even if Wolvek's "closed loop" disposable coolant circuit 12 with a pump 16 operating completely externally to the coolant circuit 12 were integrated into Fletcher's device, cooling fluid would still need to be introduced and removed from the loop in the multiple-step fashion described above utilizing the open end 18g of the tubing 18 and the petcock

90 (col. 6 ll. 20-60, col. 7 ll. 10-16); thus, the combination does not teach or suggest that the entire closed loop heating system can be operated and removed without exposing a fluid within said closed loop to the outside of the closed loop system.

Applicants also contend that one of ordinary skill in the art would not have been motivated to combine the cited references in the manner claimed. The closed loop system of the present application advantageously has a plurality of inflatable bladders configured and sized to heat and compress a breast in order to obtain biological samples from nipple aspiration fluid in order to detect and/or measure important breast disease markers (e.g., paragraph [0051]), while at the same time providing convenience in setup and operation of the device in addition to patient and device safety by keeping the fluid confined at all times during operation and removal of the device (e.g., paragraph [0121]). Neither Fletcher nor Wolvek discuss these particular problems, let alone structural features (as claimed in the present application) to solve them.

Moreover, as Claims 2 and 4-11 depend from Claim 1 and contain all of the limitations thereof in addition to further distinguishing features, Applicants submit that the rejection for these claims should be withdrawn as well.

Claim 12

Applicants also respectfully traverse this rejection and contend that Claim 12 would not have been obvious because even the combination of Fletcher and Wolvek fails to teach or suggest all of the recited claim limitations. As noted above, Claim 12 has been amended to recite an array of inflatable bladders for use in a breast pump, comprising at least a first and a second inflatable bladder in a series flow path configured to provide compression of a breast; a mechanical link between the first and second bladder; a flow path extending between the first and second bladder; a reservoir; and a flow path comprising an inflow line and an outflow line between the reservoir and the first and second bladder; said flow path comprising a movable wall such that a fluid in the system can be moved by application of external pressure to the movable wall; wherein the array is adapted to cooperate with but does not include a pump; and wherein said array can be operated with the pump and removed from operative association with the pump without exposing the fluid within said array to the outside of the array of inflatable bladders.

Applicants reiterate here the discussion of Claims 1-6 and 11 above, and contend that Fletcher does not teach or even suggest, inter alia, an array of inflatable bladders comprising at least a first and a second inflatable bladder in a series flow path configured to provide compression of a breast and wherein said array can be operated with the pump and removed from operative association with the pump without exposing the fluid within said array to the outside of the array of inflatable bladders. Wolvek does not make up for this deficiency. Therefore, because the distinct characteristics defining the array and fluid flow path are not taught or suggested in the cited prior art references even when combined, Claim 12 would not have been obvious over the combination of references cited. Applicants also reiterate that one of ordinary skill in the art would not be motivated to combine the cited references in the manner claimed. We thus request that the Examiner withdraw this rejection.

Mason in view of Wolvek

Claims 1-4, 6-11

Applicants reiterate here the discussion under the § 102(b) rejections of claims 1-6 and 11 above, and contend that Mason, even in view of Wolvek fails to teach or even suggest, inter alia, a closed loop heating system comprising a plurality of inflatable bladders in a series flow path configured to provide compression of a breast; wherein the entire closed loop heating system can be operated and removed without exposing a fluid within said closed loop to the outside of the closed loop system. As noted above, there is no teaching or suggestion that the device of Mason may be structurally configured to provide compression of a breast. Wolvek does not make up for this deficiency.

Moreover, even if Wolvek's "closed loop" disposable coolant circuit 12 with a pump 16 operating completely externally to the coolant circuit 12 were integrated into Mason's device, cooling fluid would still need to be introduced and removed from the loop in the multiple-step fashion described above utilizing the open end 18g of the tubing 18 and the petcock 90 (col. 6 ll. 20-60, col. 7 ll. 10-16); thus, the combination does not teach or suggest that the entire closed loop heating system can be operated with the pump and removed from operative association with the pump without exposing a fluid within said closed loop to the outside of the closed loop system.

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Applicants also again reiterate that one of ordinary skill in the art would not have been motivated to combine the cited references in the manner claimed. The closed loop system of the present application advantageously has a plurality of inflatable bladders configured and sized to heat and compress a breast in order to obtain biological samples from nipple aspiration fluid in order to detect and/or measure important breast disease markers (e.g., paragraph [0051]), while at the same time providing convenience in setup and operation of the device in addition to patient and device safety by keeping the fluid confined during operation and removal of the device (e.g., paragraph [0121]). Neither Fletcher nor Wolvek discuss these particular problems, let alone structural features (as claimed in the present application) to solve them.

Moreover, as Claims 2-4 and 6-11 depend from Claim 1 and contain all of the limitations thereof in addition to further distinguishing features, Applicants submit that the rejection for these claims should be withdrawn as well.

Claim 12

Applicants also respectfully traverse this rejection and contend that Claim 12 would not have been obvious because even the combination of Mason and Wolvek fails to teach or suggest all of the recited claim limitations. Applicants reiterate here the discussion of Claims 1-6 and 11 above, and contend that Mason does not teach or even suggest, inter alia, an array of inflatable bladders comprising at least a first and a second inflatable bladder in a series flow path configured to provide compression of a breast and wherein said array can be operated with the pump and removed from operative association with the pump without exposing the fluid within said array to the outside of the array of inflatable bladders. Wolvek does not make up for this deficiency. Therefore, because the distinct characteristics defining the array and fluid flow path are not taught or suggested in the cited prior art references even when combined, Claim 12 would not have been obvious over the combination of references cited. Applicants also reiterate that one of ordinary skill in the art would not have been motivated to combine the cited references in the manner claimed. We thus request that the Examiner withdraw this rejection.

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CONCLUSION

For the reasons presented above, Applicants submit that the present application is in condition for allowance and respectfully request same. If any issues remain, the Examiner is cordially invited to contact Applicants' representative at the number provided below in order to resolve such issues promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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